

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 02-220V

(To be published)

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JOSE VALLE and ANDREA VALLE, \*  
on behalf of their minor child, J.V., a minor, \*

Petitioners, \*

v. \*

SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*

Respondent. \*

\*\*\*\*\*

Filed: April 13, 2016

Vaccine Act Entitlement; Autism;  
DTaP Vaccine; Table  
Encephalopathy; Decision  
Without a Hearing.

*Jose and Andrea Valle, Miami, FL, pro se Petitioners.*

*Ryan Pyles, U.S. Department of Justice, Washington, DC, for Respondent.*

### DECISION

#### **HASTINGS, Special Master**

This is an action in which the Petitioners, Jose and Andrea Valle, seek an award under the National Vaccine Injury Compensation Program (hereinafter “the Program<sup>1</sup>), contending that their son, J.V., experienced a “Table Injury encephalopathy” following his receipt of a Diphtheria, Tetanus, and acellular Pertussis (“DTaP”) vaccination on August 2, 2000.<sup>2</sup> For the reasons set forth below, I conclude that Petitioners are *not* entitled to an award.

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<sup>1</sup> The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2012 ed.). Hereinafter, for ease of citation, all “§” references will be to 42 U.S.C. (2012 ed.). At this time, I may also refer to the Act of Congress that created the Program or the “Vaccine Act.”

<sup>2</sup> J.V.’s medical records, however, do show a diagnosis of autism spectrum disorder (“ASD”), and this claim was handled for many years through the Omnibus Autism Proceeding. As described more fully in the procedural history below, “Table encephalopathy” is not the injury that Petitioners pled in their initial petition.

## I

### THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, such as the present one, the petitioner may seek simply to demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is *presumed* to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown by the Respondent that the injury was caused by some factor other than the vaccination. (§ 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).) Cases alleging a Table Injury are now guided by the regulatory “Qualifications and aids in interpretation” (“QAI”), which provide detailed explanation of what should be considered when determining whether a vaccinee has actually suffered an injury listed on the Vaccine Injury Table. See discussion at Section VII of this Decision, below.

As relevant here, the applicable Vaccine Injury Table lists “encephalopathy” as a compensable injury, if the first symptoms thereof occur within 72 hours of the administration of a vaccination containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigens. This includes a diphtheria-tetanus-acellular pertussis (“DTaP”) vaccination. (§ 300aa-14(a)(I), as amended by 42 CFR § 100.3.)

Alternatively, if no injury falling within the Table can be shown, the petitioner may gain an award by instead showing that the vaccine recipient’s injury or death was caused by the vaccination in question.<sup>3</sup> (§ 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii).)

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<sup>3</sup> In this case Petitioners have explicitly opted *not* to pursue this alternative “cause-in-fact” method of demonstrating causation. Nonetheless, for reasons discussed below and in the interest of completeness, I will briefly address this alternative means of establishing entitlement at the end of this Decision.

## II

### BACKGROUND: THE OMNIBUS AUTISM PROCEEDING (“OAP”)

#### A. General

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as “autism” or “autism spectrum disorders” (“ASD”)<sup>4</sup> were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding (“OAP”) was developed to manage these cases within the Office of Special Masters (“OSM”). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued as “test cases” for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners’ Steering Committee (“PSC”) was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of “test cases,” exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of “test cases” during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella (“MMR”) vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant’s brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC’s *first* theory rejected the petitioners’ causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d* 88 Fed. Cl. 473 (2009), *aff’d*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V,

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<sup>4</sup> “Autism Spectrum Disorder” is a *general* classification which as of 2010 included five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger’s Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at \*5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term “autism” is often utilized to encompass *all* of the types of disorders falling within the autism spectrum. (*Id.*) I recognize that since the OAP test cases, the consensus description of ASDs, contained now in the “DSM-V” as opposed to the prior “DSM-IV,” revises the prior subcategories of ASD set forth in the first sentence of this footnote. However, the DSM-V retains the same *general description* of ASDs.

2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).<sup>5</sup> Decisions in each of the three “test cases” pertaining to the PSC’s *second* theory also rejected the petitioners’ causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The “test case” decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC’s *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC’s *second* theory (concerning vaccinations containing the preservative “thimerosal”) were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners’ claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six “test cases” concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner’s claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners’ claims that vaccines played a role in causing their child’s autism. *See, e.g., Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 19, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Holt v. HHS*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. Vowell June 24, 2015) (autism not caused by Hepatitis B vaccine); *Lehner v. HHS*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. Vowell July 22, 2015) (autism not caused by influenza vaccine); *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by

<sup>5</sup> The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

combination of vaccines); *Allen v HHS*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. HHS*, No. 03-632V (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine) (not yet published), *aff'd* 2016 WL 552481 (Fed. Cl. J. Braden Feb. 12, 2016); *Hardy v. HHS*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Hastings Nov. 3, 2015) (autism not caused by several vaccines); *Sturdivant v. HHS*, No. 07-788V, 2016 WL 552529 (Fed. Cl. Spec. Mstr. Hastings Jan. 21, 2016) (autism not caused by Hib and Prevnar vaccines); *Vernacchio v. HHS*, No. 08-504 (Fed. Cl. Spec. Mstr. Corcoran Feb. 19, 2016) (autism not caused by influenza vaccine) (not yet published) (on appeal).

In addition, some autism causation claims have been rejected *without trial*, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010) (autism not caused by multiple vaccines); *Miller v. HHS*, No. 06-753V, 2012 WL 12507077 (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013) (autism not caused by multiple vaccines); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014) (autism not caused by multiple vaccines); *Bushnell v. HHS*, No. 02-1648, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. Hastings June 12, 2015) (autism not caused by multiple vaccines); *Bokmuller v. HHS*, No. 08-573 (Fed. Cl. Spec. Mstr. Hastings June 26, 2015) (autism not caused by multiple vaccines) (not published but on Court website); *Canuto v. HHS*, No. 04-1128, 2015 WL 9854939 (Fed. Cl. Spec. Mstr. Hastings Dec. 18, 2015) (autism not caused by DTP and DTaP vaccines). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g., Fesanco v. HHS*, 99 Fed. Cl. 28 (2011) (Judge Braden affirming).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing or aggravating autism.

***B. Two cases in which children, eventually diagnosed with ASDs, were conceded or found to have suffered "Table Injuries"***

I am well aware, of course, that during the years since the "test cases" were decided, in two cases involving vaccinees suffering from ASDs, Vaccine Act compensation was granted. But in *neither* of those cases did the Respondent concede, nor did a special master find, that there was any "*causation-in-fact*" connection between a vaccination and the vaccinee's ASD. Instead, in both cases it was conceded or found that the vaccinee displayed the symptoms of a *Table Injury* within the Table time frame after vaccination. (*See* Section I above).

In *Poling v. HHS*, the presiding special master clarified that the family was compensated because the Respondent conceded that the Poling child had suffered a *Table Injury*--not because the Respondent or the special master had concluded that any vaccination had contributed to causing or aggravating the child's ASD. *See Poling v. HHS*, No. 02-1466V, 2011 WL 678559,

at \*1 (Fed. Cl. Spec. Mstr. Jan. 28, 2011) (a fees decision, but noting specifically that the case was compensated as a Table Injury).

Second, in *Wright v. HHS*, No. 12-423, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a “Table Injury” after a vaccination. However, she stressed that she was *not* finding that the vaccinee’s ASD in that case was “caused-in-fact” by the vaccination--to the contrary, she specifically found that the evidence in that case did *not* support a “causation-in-fact” claim, going so far as to remark that the petitioners’ “causation-in-fact” theory in that case was “absurd.” (2015 WL 6665600 at \*2.)

The compensation of those two cases, thus does *not* afford any support to the notion that vaccinations can contribute to the *causation* of autism. In setting up the Vaccine Act compensation system, Congress forthrightly acknowledged that the Table Injury presumptions would result in compensation for some injuries that were *not*, in fact, truly vaccine-caused. H.R. Rept. No. 99-908, p. 18, 1986 U.S.C.C.A.N. 6344, 6359. (“The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.”)

### ***C. Relevance of other ASD cases to this case***

In this case, the primary issue raised by the Petitioners is *not* whether vaccines *caused* J.V.’s severe neurological disorder, which has been characterized as a form of ASD. In this case the primary<sup>6</sup> question is whether J.V. suffered a *Table Injury*, namely “encephalopathy,” with the first symptoms of that encephalopathy occurring within a Table time period after vaccination. I ultimately conclude below that J.V. did *not* suffer a Table encephalopathy. But it should be stressed that the evidence upon which I have relied in making my decision is limited to the evidence set forth *in this case*, on the issue of whether J.V. experienced a “Table Injury encephalopathy,” or suffered any injury that was “caused-in-fact” by any vaccines. I include the above description of the OAP primarily to show why this case, filed in 2002, was not processed in the usual manner of non-autism Program cases. Because this case involved a child who had been diagnosed with a form of autism, the processing of this case was delayed, along with the other 5,000-plus autism cases, to await the final outcome of the autism “test cases.” (When Petitioners filed this case on March 20, 2002, it should be noted, their petition *did not* allege a Table Injury at all, but rather indicated only that a vaccine reaction had interfered with their son’s development.) However, the OAP discussion *also* demonstrates that all other Program

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<sup>6</sup> Particularly because this is a *pro se* case, this Decision also addresses additional theories of causation which are arguably suggested by, although not explicitly raised in, Petitioners’ pleadings. For example, at earlier stages of this case Petitioners raised a Table “anaphylaxis” claim, before subsequently characterizing J.V.’s injury as encephalopathy. In addition, although Petitioners ultimately relied solely on a “Table encephalopathy” claim, they have also alleged as causal certain vaccines for which encephalopathy is not a Table Injury. For that reason, in the interest of completeness, I have addressed Petitioners’ *potential* “cause-in-fact” claim.

claimants have failed, as did the Petitioners here in their alternative “cause-in-fact” argument, to provide *any* persuasive evidence that vaccines can cause or aggravate ASDs.

### III

#### PROCEDURAL HISTORY OF THIS CASE

Petitioners filed their claim *pro se*<sup>7</sup> on March 20, 2002. (Original Petition, ECF No. 1.) That petition, which was accompanied by two volumes of medical records, alleged that J.V. experienced an adverse reaction to vaccinations received about 18 months before the petition was filed. (ECF No. 1, p. 1.) That petition also suggested that J.V. experienced a post-vaccination change in behavior and development, and identified DTP, DTaP, Hib and Polio vaccines as potentially causal. (*Id.*) Since J.V. suffered from an autism spectrum disorder, the case was stayed while “general causation” issues were litigated in the OAP test cases.

On January 15, 2009, Special Master Denise K. Vowell<sup>8</sup> issued an order updating Petitioners on the status of the OAP and explaining that their case would proceed in two stages, the first stage intended to determine whether their claim was timely filed, and a second stage intended to provide petitioners with timely-filed claims an opportunity to complete the medical record. (ECF No. 20.) Petitioners subsequently filed medical records marked as Exhibits 1 to 13 on April 14, 2009, and records marked as Exhibit 14 on May 19, 2009. (*See* ECF Nos. 26, 103, 28.)

On July 1, 2009, Respondent filed a notice indicating that this case was timely filed and did not oppose continued inclusion in the OAP. (ECF No. 30.) Special Master Vowell ordered Petitioners to complete the medical records and file a statement of completion. (ECF No. 31.) Petitioners filed further records marked as Exhibits 15 and 16 on October 5, 2009, and Exhibit 17

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<sup>7</sup> Although Petitioners initially proceeded *pro se*, they subsequently retained counsel at various times during the pendency of this case, before finally returning to *pro se* status after the withdrawal of their most recent counsel on August 26, 2015. In all they have had five attorneys representing them at different points. Those five attorneys were Clifford Shoemaker, counsel of record from November 11, 2002, until July 14, 2004; Thao Ho, counsel of record from July 14, 2004, until March 16, 2009; Harry G. Potter, III, counsel of record from March 16, 2009, until May 14, 2012; John Sutton, counsel of record from September 27, 2012, until October 24, 2013; and Edward Kraus, counsel of record from June 4, 2014, until August 26, 2015. At all other times Petitioners proceeded *pro se*.

<sup>8</sup> This case, like virtually all of the 5,400 autism-related cases, was initially assigned to my docket. Subsequently, many of the autism cases were transferred to two other special masters to be processed as part of the OAP. This case was transferred to Special Master Vowell on February 8, 2007, and remained on her docket until it was transferred back to me on August 5, 2015, in anticipation of Special Master Vowell’s retirement.

on December 2, 2009. (ECF Nos. 32, 104, 35.) They filed a statement indicating that the medical records were complete on December 2, 2009.<sup>9</sup> (ECF No. 36.)

On November 7, 2011, Petitioners were informed of the outcome of the OAP test cases, and instructed to determine whether they wished to pursue their claim further. (ECF No. 37.) Petitioners indicated that they wished to proceed. (ECF No. 38.)

Petitioners were instructed to file a written causation statement (ECF No. 48), which they did on July 3, 2012 (ECF No. 52). In this statement, entitled “Narrative,” Petitioners characterized J.V.’s injury as an “anaphylactic shock,” and specifically alleged that it constituted a Table Injury, having occurred within four hours of vaccination. (ECF No. 52, p. 1.) The narrative specified that the vaccines at issue were DTP, IPV, and HIB, all administered on August 2, 2000. (*Id.*) Petitioners claimed that J.V.’s developmental delay and regression, ultimately resulting in a diagnosis of autism, were the result of an allergic reaction to his vaccinations. (*Id.*, p. 2.)

On July 25, 2012, Petitioners filed further records marked as Exhibits 20 and 21. (ECF No. 54.) Petitioners filed an affidavit by J.V.’s pediatric neurologist, Dr. Trevor Resnick, along with additional medical records, all without exhibit designation, on September 27, 2012. (ECF No. 59.) On January 7, 2013, Petitioners filed an updated exhibit list that designated Dr. Resnick’s affidavit as Exhibit 22, and the accompanying medical records as Exhibits 23 to 26. (ECF No. 65-1.) At that time, Petitioners also filed as Exhibit 27 a letter statement from Dr. Rolando Nunez, an asthma and allergy specialist. (ECF No. 65.) On January 15, 2013, Petitioners filed a statement indicating that all obtainable and relevant medical records had been filed. (ECF No. 66.)

Petitioners filed an Amended Petition on January 31, 2013. (ECF No. 67.) That Amended Petition alleged that J.V.’s vaccinations of August 2, 2000, identified as “Hibtitier,” “Acel-Imune,” and Polio, resulted in a Table Injury of “encephalitis.” (ECF No. 67, p. 5.) The Amended Petition alternatively pled that J.V. experienced a “neurologic deficit” that was caused-in-fact by these vaccines. (*Id.*, p. 8.) Accompanying their amended petition, Petitioners filed an affidavit by J.V.’s pediatrician, Dr. Pelaez, which they designated as Exhibit A. (ECF No. 67-1.) Petitioners filed a supporting affidavit by Ms. Valle on February 20, 2013. (ECF No. 69.)

On March 22, 2013, Special Master Vowell conducted a status conference in which she indicated that the evidence in the record was insufficient to meet Petitioners’ burden of proof relative to either a Table Injury or a cause-in-fact claim. (ECF No. 70, p. 2.) Petitioners were ordered to file an expert report. (*Id.*) In response, Petitioners filed a neurology consultation report by Dr. Roberto Tuchman, an affidavit by Rolando Nunez, and a curriculum vitae for Dr. Nunez.<sup>10</sup> (ECF No. 73.)

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<sup>9</sup> Subsequently, in an order dated June 7, 2012, Special Master Vowell created an Exhibit List identifying all of Petitioners’ previously filed exhibits. (ECF No. 48.) In that list, the Special Master designated the two volumes of records filed with the petition as Exhibits 18 and 19. (*Id.*, p. 4.)

<sup>10</sup> These documents were attached as Exhibits A and B to an affidavit by Mrs. Valle. Dr. Nunez’s CV was attached to Exhibit B. (ECF Nos. 73-1, 73-2.)



Respondent filed her “Rule 4(c) report” on September 16, 2013, taking the position that compensation is not appropriate in this case. (ECF No. 81.) Respondent’s report was accompanied by an expert report and curriculum vitae of Catherine Shaer, M.D., a pediatrician and medical officer with the Division of Vaccine Injury Compensation at the Department of Health and Human Services. (Exs. D, E.)<sup>11</sup>

In a status report filed on February 3, 2014, Petitioners indicated that they intended to file further family statements and medical literature, but that they would not seek evidence from any further experts, relying instead on the affidavits of Drs. Resnick, Nunez, and Palaez. (ECF No. 97.) On March 7, 2014, Petitioners filed a statement by Mr. Valle, along with information regarding encephalitis as well as DTaP, Polio, and Hib vaccines. (ECF Nos. 98, 98-1 to 98-5.) Mr. Valle’s statement was marked as Exhibit 35, and the information on encephalitis as Exhibit 36. (ECF No. 98.) Exhibit designations were not given to the vaccine information attachments.

Petitioners subsequently attempted to obtain a supplemental report from Dr. Resnick, but their counsel was unable to secure his cooperation. (ECF Nos. 105-111.) During a status conference on February 5, 2015, Petitioners requested, through their attorney, the opportunity to proceed to a “fact hearing” prior to submitting a supplemental expert report. (ECF No. 111.)

A fact hearing was scheduled for March 3, 2015, in Miami, Florida. (ECF No. 112.) However, during a status conference on February 23, 2015, Petitioners’ counsel informed the court that Petitioners no longer desired a hearing, and would instead prefer a ruling on the written record. (ECF No. 115.) Petitioners indicated that a hearing would be too stressful, both emotionally and physically. (*Id.*) The parties were ordered to file proposed findings of fact and conclusions of law. (*Id.*)

Because of Petitioners’ inconsistent exhibit designations as well as several docketing errors, Special Master Vowell issued a final comprehensive exhibit list on February 24, 2015. (ECF No. 116-1.) She instructed the parties to use that list’s exhibit designations in their filings regarding proposed findings of fact and conclusions of law. (ECF No. 116.) ***This Decision will likewise use the exhibit designations contained in Special Master Vowell’s exhibit list of February 24, 2015.***

Petitioners filed their Proposed Findings of Fact and Conclusions of Law on April 24, 2015. (ECF No. 117.) Petitioners requested a finding that they are entitled to compensation based on their contention that “J.V. suffered a table encephalopathy following the DTaP vaccine he received on August 2, 2000, and no alternative cause has been suggested by respondent.” (ECF No. 117, p. 13.) Petitioners further indicated that “the issue in this case is not whether vaccines can cause autism, but whether JV suffered an acute encephalopathy and then a chronic

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<sup>11</sup> Although these were the first exhibits Respondent filed, these designations of D and E were chosen because Petitioners had previously marked exhibits as A, B, and C. (ECF No. 81, p. 3, fn. 3.) In an order filed January 2, 2014, Special Master Vowell issued a corrected exhibit list in order to remedy Petitioners’ irregular exhibit designations. (ECF No. 96-1.) She did not, however, change respondent’s designations.

encephalopathy that persisted for more than six months. Regardless of whether JV carries an autism diagnosis, his social and communication deficits that did not exist prior to his vaccinations are evidence of an encephalopathy which caused a changed mental state that persisted for more than six months.”<sup>12</sup> (*Id.*)

Respondent filed a Response to Proposed Findings of Fact and Conclusions of Law on May 11, 2015. (ECF No. 120.) Respondent concluded: “Inasmuch as petitioners have not provided reliable evidence sufficient to establish that [J.V.]’s August 2, 2000 DTaP vaccination resulted in a Table encephalopathy (and they have not established a cause-in-fact case under *Althen*), respondent requests that this case be dismissed.” (ECF No. 120, p. 9.)

After this case was transferred to me, Petitioners requested a status conference to receive an update on the status of their claim. (ECF No. 132.) In an order dated November 3, 2015, I did not schedule a status conference, but informed Petitioners that I was aware of their request for a ruling on the written record without an evidentiary hearing, and that I intended to decide their case on that basis as soon as practicable. (ECF No. 133.)

On December 23, 2015, Petitioners filed a letter dated December 12, 2015, in which they responded to my order of November 3, 2015.<sup>13</sup> (ECF No. 134.) Petitioners stated that their decision to decline an evidentiary hearing and request a decision on the written record was made at the recommendation of their former attorney, Mr. Kraus. (*Id.*) Petitioners further indicated that Mr. Kraus “quickly shut down all additional evidence that could be submitted without our knowledge.” (*Id.*) However, Petitioners’ letter did not request an evidentiary hearing or any other course of action. (*Id.*) Nor did Petitioners deny that they had previously declined a hearing. (*Id.*) Instead, Petitioners suggested only a concern that the court does not have

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<sup>12</sup> Petitioners later filed a letter which may arguably suggest that Petitioners do not have full confidence in the attorney who prepared this submission. (*See* ECF No. 134). However, I note that Petitioners’ most recent supplemental statement of causation, submitted *pro se* in response to Special Master Vowell’s Scheduling Order of January 2, 2014 (ECF No. 97), likewise indicated that Petitioners wished to pursue a Table Injury encephalopathy claim. (*See* Status Report dated 2/3/2014 (ECF No. 97).) Significantly, however, Petitioners also alleged that J.V.’s injury was *caused* by his polio and Hib vaccines in addition to his DTaP vaccine. (*Id.*) Encephalopathy is not a Table injury relative to those other two vaccines. 42 C.F.R. § 100.3. Thus, I will also, notwithstanding the statements made in the Petitioners’ Proposed Finding of Fact and Conclusions of Law restricting this case to a Table Injury claim, address whether the facts of this case warrant a finding of causation-in-fact.

<sup>13</sup> Because Petitioners expressed surprise at the course of this case, including the fact that I (and not Special Master Vowell) would be deciding the case, and because they have claimed not to have received unspecified orders from the court, I note that the address included in Petitioners’ letter of December 12, 2015 (ECF No. 134) matches the address reflected on the docket of this case. I further note that Petitioners’ letter explicitly confirms their receipt of my order of November 3, 2015, and that they specifically and correctly addressed their prior request for a status conference to me and not Special Master Vowell following the transfer of this case. (ECF No. 132.)

statements from J.V.'s grandmother or sister.<sup>14</sup> (*Id.*) I have considered Petitioners' most recent submission, and find that this case is nonetheless ripe for a decision on the written record and without a hearing.<sup>15</sup>

<sup>14</sup> To the extent that Petitioners intimate that Mr. Kraus stymied their prosecution of this case, I do not find that assertion credible based on the record before me. The record reflects that during the relatively short period of time that Mr. Kraus acted on behalf of Petitioners, he expended significant effort attempting to move the case forward to hearing, and made extensive efforts to gain the cooperation of Petitioners' proposed expert, Dr. Resnick. Moreover, this case was filed *more than 12 years* prior to Mr. Kraus' involvement. Indeed, Petitioners proceeded on a *pro se* basis for a period of seven months immediately preceding Mr. Kraus' notice of appearance. During that period, Petitioners were cautioned that they were themselves responsible for responding to court orders (*see* Order, 10/24/2013 (ECF No. 88)), and were ordered to identify any additional evidence they wished to file (*see* Scheduling Order, 1/2/2014 (ECF No. 96)). Although Petitioners specifically identified statements by J.V.'s grandmother and siblings as well as Mr. Valle as evidence to be filed (*see* Status Report, 2/3/2014 (ECF No. 97)), they proceeded only to file medical literature and an affidavit by Mr. Valle, and not any additional statements or affidavits by either J.V.'s grandmother or any of his siblings (*see* Status Report, 3/7/2014 (ECF No. 98)). Thus, it is not accurate for Petitioners to suggest that Mr. Kraus is responsible for their failure to have these additional statements included in the record of this case. Petitioners had ample opportunity to file them along with their other submitted evidence, and apparently declined or neglected to do so. I further note that, despite expressing concern that these additional statements are not within the record, Petitioners made no attempt to file the statements subsequent to Mr. Kraus being terminated as counsel of record. In any event, these statements are unlikely to be helpful in resolving this case. Even if Mr. and Mrs. Valle's accounts were fully corroborated by these close family members, I would still find it significant that the accounts are inconsistent with the contemporaneous medical records.

<sup>15</sup> Even if Petitioners' most recent letter were to be interpreted as a request for a hearing (which it did not appear to be), Vaccine Rule 8(d) specifies that "the special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." And, as I noted in Section II, above, former OAP cases have been dismissed without a hearing over petitioners' objections where submissions reflect a lack of plausible proof regarding vaccine causation. Based on the record of this case, I would find such an approach to be appropriate here. I note in particular that, as described above, Special Master Vowell held a status conference on March 22, 2013, in which she explained that the evidence then in the record was *insufficient* to meet Petitioners' burden. (ECF No. 70, p. 2.) *See, e.g., Dickerson v. HHS*, 35 Fed. Cl. 593 (1996) (explaining that even in a Table injury case, a medical opinion is still necessary to categorize the reactions described by petitioner as actual symptoms or manifestations of the alleged injury). Petitioners subsequently indicated in a status report, while acting *pro se*, that they intended to rely on the *written* opinions of Drs. Resnick, Nunez, and Palaez, that were previously filed, and that they "are not seeking additional evidence from any more experts." (ECF No. 97, p. 1.) It was only Mr. Kraus's later, and ultimately unsuccessful, attempts to gain Dr. Resnick's cooperation as a *testifying* expert that prolonged this case and prevented an earlier decision on the written record. (*See* ECF Nos. 105-111.) I have considered the written opinions submitted by Petitioners, but after years of litigation Petitioners have not secured a *testifying* expert witness. Thus, the idea that a hearing would be helpful is speculative

## IV

### FACTUAL HISTORY OF THIS CASE

#### *A. History contained in J.V.'s medical records*

##### *1. Prior to 15 months of age*

J.V. was born on May 5, 1999, following a full term pregnancy. (Ex. 3, p. 1.) There were no complications. (*Id.*)

On May 12, 1999, at one week of age, J.V. received his first Hep B vaccination. (Ex. 18, p. 2; Ex. 20, pp. 2-3.<sup>16</sup>) His next visit was on May 28, 1999. (Ex. 20, p. 4.) Although noted as a “sick visit,” the visit was merely a follow up regarding J.V.’s weight gain. (Ex. 20, p. 4; Ex. 14, p. 2.) He was noted to be “doing great.” (Ex. 20, p. 4.)

During a sick visit on July 1, 1999, J.V. was seen for a cold and mild loose stools. (Ex. 20, p. 5.) He was diagnosed as having acute gastroenteritis (“AGE”), but, he was still “alert, smiling,” and had excellent weight gain. (*Id.* at 6.) His second Hep B vaccine was held. (*Id.*)

On July 20, 1999, J.V. was seen for a two-month well child visit. (Ex. 20, p. 6.) He was noted to be alert and doing well, and there were no behavioral concerns. (*Id.*) At this visit he received his first DTaP, HIB, and IPV vaccinations, as well as his second Hep B vaccination. (Ex. 18, p. 2; Ex. 20, p. 6.)

J.V. was next seen on August 30, 1999, for a sick child visit. (Ex. 20, p. 7; Ex. 14, p. 2.) He was noted as having a cough, runny nose, wheezing, loss of appetite, and loose stools. (Ex. 20, p. 7.) His diagnosis was upper respiratory infection (“URI”) and acute gastroenteritis. (*Id.*; Ex. 14, p. 2.)

On September 16, 1999, J.V. had a four-month well exam. (Ex. 20, p. 8.) He received his second DTaP, HIB, and IPV vaccinations. (Ex. 20, p. 8; Ex. 18, p. 2.) His record notes that he had no contraindications to vaccination at that time. (Ex. 20, p. 8.)

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at best. *See, e.g., Hovey v. HHS*, 38 Fed. Cl. 397, 401 (1997)(noting that “petitioners did not make representations that testimony at an evidentiary hearing would be anything other than evidence already contained in the affidavits, medical records and doctors' letters which were previously submitted. After reviewing the record, the special master could reasonably conclude that there is nothing a witness could testify to at an evidentiary hearing that would affect the outcome of the case. Thus, the special master acted within his discretion in denying the evidentiary hearing.”)

<sup>16</sup> Certain medical records, including the lengthy Ex. 20, were filed by Petitioners on July 25, 2012, while they were *pro se*, without page numbers. Accordingly, Special Master Vowell ordered the Clerk of this Court to “add computerized page numbers to those records” and create a compact disc thereof. (ECF No. 54.) My references to page numbers in Ex. 20 are to those computerized page numbers.

J.V. was not seen again until November 27, 1999. (Ex. 20, p. 9; Ex. 14, p. 2.) At that time he reportedly had a cold for a few days with cough, nasal congestion, and ear ache. (Ex. 20, p. 9.) However, he was noted to be happy and alert. (*Id.*) He was prescribed Albuterol and Amoxicillin. (Ex. 20, p. 10.) J.V. was seen again for a sick visit on February 8, 2000. (Ex. 20, p. 11.) He had ear ache, cough, trouble breathing, and loose stools. (*Id.*) He was prescribed Zithromax, Albuterol, and Auralgan. (*Id.*, p. 12.) Two days later, on February 10, 2000, J.V. was seen for a follow-up. (*Id.*, p. 13.) His cough had improved on Albuterol, but he had developed a rash following Zithromax. (*Id.*)

J.V. had a nine-month well visit on February 16, 2000. (Ex. 20, p. 15.) J.V. was noted to be crawling, standing, and saying “dada.” (*Id.*) Vaccinations were held due to illness. (*Id.*) Noted concerns included flu, otitis media (ear infection), and cough. (*Id.*) He was put on Amoxicillin. (Ex. 20, pp. 15-16.) At a sick visit on March 3, 2000, J.V. had a cough, occasional sneezing, and sometimes pulled his ears, though his otitis media was noted to be resolved. (Ex. 20, p. 17.) At this visit, Amoxicillin was added to J.V.’s listed allergies. (*Id.*) His vaccinations were noted to be held for another week. (*Id.*) At another sick visit on March 10, 2000, J.V. was seen again for fever and earache. (*Id.*, p. 19.) He was noted to be pulling on his ears, coughing, having a runny nose, and having trouble sleeping. (*Id.*) His diagnosis was otitis media and upper respiratory infection. (*Id.*) J.V. had further sick visits on May 3, 2000, and May 23, 2000. (Ex. 20, pp. 21-24.)

Thus, in general, prior to J.V.’s 15-month well-child visit, J.V. was generally described as a smiling and alert baby, though he was often ill with fevers, earaches, and coughs. (Ex. 20, pp. 2-24.) There are no notes in the medical records regarding any adverse reactions of J.V. to his vaccinations between birth and his 15-month well-child visit. (*Id.*)

## ***2. J.V.’s 15-month well exam, and first reports of a vaccine reaction***

At his 15-month well child visit on August 2, 2000, J.V. was scheduled to receive the DTaP, Haemophilus influenza type B (Hib), Inactivated Polio (IPV), Hepatitis B (Hep B), Measles, Mumps, Rubella (MMR), and Varicella (VARI) vaccines. (Ex. 20, p. 25.) The record for that visit indicates that J.V. was negative at that time for any vaccine contraindication. (*Id.*) In addition, Mrs. Valle completed a medical history form at that time that indicated that J.V. was allergic only to milk. (*Id.*, p. 26.) Nonetheless, it was noted that “mom only wants to give 3 vaccines today. Will come back next week for the others.” (*Id.*, p. 25.) Thus, at the visit on August 2, 2000, J.V. received only the DTaP, Hib, and IPV vaccines. (*Id.*) J.V. was noted to be able to say the words “mama,” “daddy,” and “what’s that.” (*Id.*) He was also able to wave “bye-bye.”<sup>17</sup> (*Id.*)

J.V. was next seen on November 16, 2000, three months after he received the allegedly harmful vaccinations. (Ex. 20, p. 27.) The chief complaint was earache. (*Id.*) The history taken at this appointment stated that J.V. was “pulling on both ears, also mother indicates [patient] stopped speaking after last vaccines. Mother indicates 6 other children in family have speech

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<sup>17</sup> Petitioners interpret this record as reporting that J.V. could say bye-bye (ECF 117, p. 2), but the record actually states that he “waves bye-bye.” (Ex. 14, p. 75; Ex. 20, p. 25.)

delay problems[,] however oldest has outgrown [unintelligible] and doing very well.” (*Id.*) J.V.’s diagnosis was teething and speech delay. (*Id.*) J.V. was referred for an audiology evaluation. (*Id.*)

On January 2, 2001, J.V.’s mother reported to J.V.’s pediatrician, Dr. Gloria Pelaez, that she believed that J.V. “had an allergic reaction to vaccinations back in August.” (Ex. 20, p. 28.) His mother reported that his symptoms back in August were mild swelling around his eyes (“periorbital edema”), an unspecified type of rash, “less activity than usual,” and loss of speech. (*Id.*, pp. 28-29.) J.V.’s mother confirmed that she did not seek medical attention at the time that these symptoms occurred, wishing instead to see “if child would improve on his own and return to normal.” (*Id.*, p. 29.)

Dr. Pelaez also recorded in her notes on January 2, 2001, that she was contacted by medical personnel from “Tallahassee” (referring to Florida state government) regarding the need for a Vaccine Adverse Event Report (“VAERS”), but then noted that no medical attention had been sought at the time of the reported vaccine reaction, and no medical personnel observed the reported vaccine reaction. (Ex. 20, p. 29.) Dr. Pelaez also noted a “strong” family history of both learning disability and allergies. (*Id.*) She referred J.V. for genetic and allergy evaluations “to see if there may be an underlying genetic problem that may be responsible for learning disabilities.” (*Id.*)

Nonetheless, Dr. Pelaez submitted a VAERS report on January 12, 2001. (Ex. 14, p. 65.) Dr. Pelaez reported the history provided by Mrs. Valle, but noted that no medical attention had been sought and that there is a family history of speech delay.<sup>18</sup> (*Id.*) J.V.’s mother also filled out a VAERS report, although it is not dated. (*Id.*, p. 66.) The report completed by J.V.’s mother describes J.V.’s symptoms as “very tired like he had the flu, swollen eyes[;] red spot (not a rash)[;] would not talk just wanted to sleep[;] did not want to play. Spot lasted about 24hr. swollen eyes about 24hr. no temp; Has not spoken since date of shots.”<sup>19</sup> (*Id.*)

### **3. Subsequent medical history**

J.V.’s hearing was evaluated on January 24, 2001, and was found to be within normal limits. (Ex. 14, p. 32.) On January 25, 2001, he underwent allergy testing at the Florida Center for Allergy and Asthma Care. (Ex. 14, p. 31; Ex. 20, pp. 32-33.) No positive allergies were found, and it was noted that his hives were unlikely to be due to dairy or eggs.<sup>20</sup> (Ex. 20, p. 33.)

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<sup>18</sup> For some unknown reason, Dr. Pelaez also apparently filled out another VAERS report. (Ex. 14, p. 99.) That report is undated, but it reported information from J.V.’s mother similar to that contained in Dr. Pelaez’ other VAERS report, and, again, repeated that J.V.’s reported reaction was not observed by any medical personnel. (*Id.*)

<sup>19</sup> An additional copy of Mrs. Valle’s VAERS report, on which the date of completion is included, was also filed. (Ex. 17, p. 7.) However, the date of completion is illegible. (*Id.*) The form is also stamped as received. The day and year are not visible, but it was received in July, suggesting that it was submitted at the earliest close to a year after J.V.’s 15-month vaccinations. (*Id.*)

<sup>20</sup> Citing a record at Ex. 6, p. 4, Petitioners contend that J.V. tested positive for a milk allergy. (ECF No. 117, p. 5.) Although the cited record does state “milk only,” I do not read this

On January 26, 2001, J.V.'s pediatric records indicate that his mother sought a neurology referral due to "borderline autism" and "lack of speech." (Ex. 20, p. 40.) J.V. was reported as having "less than 4 words." (*Id.*) On February 21, 2001, J.V.'s pediatrician diagnosed him as having "speech delay," and noted that referrals for speech and neurology evaluations were pending. (Ex. 20, p. 38.)

On January 27, 2001, J.V. presented at the emergency room for treatment of a fever. (Ex. 8, p. 129.) His diagnosis was unspecified viral infection. (*Id.*)

J.V. was first seen by neurologist Trevor Resnick, MD, on March 7, 2001. (Ex. 19, pp. 42-45.) Dr. Resnick assessed J.V. as having "social-communicative disorder," and ordered an EEG to rule out epileptic aphasia, blood DNA testing to rule out Fragile-X, and an MRI to rule out congenital structural pathology. (Ex. 19, p. 45.) These tests all showed results considered normal. (Ex. 19, pp. 46-47; Ex. 14, pp. 11, 22.) Dr. Resnick's assessment remained "social communicative disorder." (Ex. 14, p. 11.)

On June 1, 2001, J.V. was seen for a two-year well visit. (Ex. 20, p. 42.) J.V. was noted to be speech delayed, and was referred for speech evaluation. (*Id.*) Mrs. Valle refused vaccinations at this visit and requested a referral to a new allergist. (*Id.*)

On October 28, 2001, J.V. was seen in the emergency room for an ear infection. (Ex. 8, p. 115.)

On January 3, 2002, J.V. was seen for a speech and language assessment. (Ex. 19, pp. 39-41.) At two years and eight months of age, J.V. showed receptive language skills up to the seven-month-old level, and expressive language skills as the 5-month-old level. (*Id.*, p. 40.) Some aspects of the overall evaluation were incomplete due to non-compliance. (*Id.*) The diagnostic impression indicated that "based on clinical observations and parental report, [J.V.] demonstrates a significant receptive-expressive language disorder coupled with decreased engagement/social interaction skills, limited play skills and decreased frustration tolerance." (*Id.*, p. 41.)

On January 31, 2002, J.V. was noted by his pediatrician to have speech delay, and as displaying "autistic-like behaviors," specifically moaning. (Ex. 20, p. 50.)

In July and August of 2002, J.V. underwent neurodevelopmental screening. (Ex. 9.) He was found to be "severely autistic" based on the Childhood Autism Rating Scale (CARS). (Ex. 9, p. 2.) Overall, the results of the screening indicated that "significant behavior, social-communication, and adaptive behavior deficits are evident. The presence of these behaviors and their intensity is consistent with the diagnosis of Autism." (Ex. 9, p. 3)

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notation as reflecting a positive result on the allergy test. (Ex. 6, p. 4.) Rather, the testing chart has marked "neg" next to the milk test, which is circled. Taken as a whole, I interpret this record as indicating that J.V. was allergy-tested for "milk only," and that his result was negative. (*Id.*) This interpretation is consistent with the allergist's subsequent summary report, which stated that J.V. was "negative to milk" on skin test. (Ex. 6, p. 8.)

On November 15, 2002, J.V. was seen in the emergency room for ear pain and excessive crying. (Ex. 8, p. 95.) On May 15, 2003, J.V. was once again seen at the emergency room, for cellulitis and abscess with swelling of the leg following an insect bite. (*Id.*, p. 5.)

On July 27, 2004, J.V. was evaluated by neurologist Roberto Tuchman, M.D., of Miami Children's Hospital. (Ex. 20, pp. 61-62.) Dr. Tuchman took a history in which it was reported that J.V. developed well until his 15-month vaccinations, after which he regressed in language and social communication. (*Id.*, p. 61.) He was described as being in good health other than an allergy to insect bites and a four-day hospitalization about a year prior. (*Id.*) Dr. Tuchman noted that motor milestones were met at a normal age, but that J.V. exhibited "hand-flapping," limited interest in toys with little imaginative play, and "extremely limited" ability to engage others, with no verbal output and no non-verbal communication. (*Id.*) Dr. Tuchman's impression was "deficits at the level of language and social communication consistent with the diagnosis of autism." (*Id.*, p. 62.)

In addition to the above, the record of this case contains many additional records relating to J.V.'s speech therapy as well as many other later evaluations related to his education and social services available to him. (*See, e.g.*, Exs. 12, 13, 15.)

#### ***B. Additional facts alleged by J.V.'s parents***

In addition to the above-discussed medical records, Mr. and Mrs. Valle provided written statements in this case further describing the events surrounding J.V.'s vaccinations and alleged vaccine injury. Specifically, Petitioners filed a "narrative" statement by Mrs. Valle dated June 24, 2012 (*see* Ex. 40), as well as an affidavit by Mrs. Valle dated February 19, 2013 (*see* Ex. 29). Subsequently, on March 7, 2014, Petitioners also filed an undated written statement by Mr. Valle. (*See* Ex. 34.)

In her "narrative" statement, Mrs. Valle stated that J.V. has a background of severe allergies, and that both she and her other children have experienced adverse vaccine reactions.<sup>21</sup> (Ex. 40, p. 1.) With regard to J.V. in particular, both Mr. and Mrs. Valle stated that J.V. had a history of vaccine reactions *pre-dating* the vaccinations of August 2, 2000, which are implicated by the instant claim. (Ex. 34, p. 1.; Ex. 40, p. 1.) Specifically, they stated that following each vaccination, J.V. would experience flu-like symptoms, including loss of appetite and fever. (*Id.*) Mrs. Valle further indicated that these symptoms progressed, so that "within months" (it is not clear within months of *what*) J.V. "was placed on a nebulizer due to difficulty breathing." (Ex. 40, p. 1.) Mr. Valle also reported that J.V.'s formula had to be changed each time he received vaccinations. (Ex. 34, p. 1.)

Contrary to these narratives, however, there is no report in the medical records that J.V. experienced any reaction to any of his early childhood vaccinations. (*See* Ex. 20.) Moreover, at J.V.'s September 16, 1999, office visit, it was specifically noted that he had no contraindication for vaccination. (Ex. 20, p. 8.)

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<sup>21</sup> Mrs. Valle's description of vaccine reactions among her other children is consistent with fever, which is a common occurrence following vaccination.



In relation to Mrs. Valle's report that J.V. was "placed on a nebulizer," I note that J.V. was first prescribed Albuterol on November 27, 1999. (Ex. 20, p. 10.) This prescription was not attributed to any vaccine reaction, but rather was in treatment of a cold with cough and nasal congestion. (*Id.*, p. 9.) J.V. had presented with cough and congestion on that date, with onset reported as just a "few days" prior. (*Id.*) Similarly, although J.V. did on occasion switch formulas, there is no indication that such a change was in any way related to any vaccine-reactions. (*See, e.g.*, Ex. 20, pp. 5, 7.) Nor do the changes appear to be temporally related to J.V.'s vaccinations in any way. (*Id.*)

Most significant to the instant claim are Mr. and Mrs. Valle's accounts of the events following J.V.'s vaccinations of August 2, 2000. Mrs. Valle's narrative seems to indicate that after J.V. arrived home, he seemed tired and she put him to bed. (Ex. 40, p. 1.) She stated that after she put him to bed, he slept through the night without fever or difficulty breathing. (*Id.*) Mr. Valle stated that the family was instructed to remain at the pediatrician's office for 20 minutes to determine if J.V. would have a vaccine reaction. (Ex. 34, p. 1.) He indicated that J.V. became lethargic at that time and remained in that condition (for how long is not specified). (*Id.*)

Mrs. Valle further averred that the next day J.V. developed spots on his face and his upper body which she described as looking "like an octopus was sucking on his skin." (Ex. 40, p. 2.) She stated that his eyes were also swollen, but that he was not crying and did not have a fever or swelling at the injection site. (*Id.*) Mr. Valle offered a similar description, placing this reaction as happening at some point within 48 hours of vaccination. (Ex. 34, p. 1.)

Both of J.V.'s parents averred that Mrs. Valle called J.V.'s pediatrician the morning of his alleged vaccine reaction and spoke with a nurse. (Ex. 34, p. 1.; Ex. 40, p. 2.) J.V.'s medical records, however, contain no notation reflecting any such call.<sup>22</sup> Further, the allergic-type symptoms reported in Exs. 29, 34, and 40 were not recorded during J.V.'s next office visit, on November 16, 2000, although Mrs. Valle then reported that J.V. had "stopped speaking" since his August vaccinations. (Ex. 20, p. 27.) Moreover, when Mrs. Valle first reported, on January 2, 2001, the details of J.V.'s alleged allergic reaction of August 2-3, 2000, Dr. Pelaez not only failed to reference any prior call or report, but also noted that "mom didn't bring child to medical attention [in August] because she wanted to see if child would improve on his own and return to normal." (Ex. 20, p. 29.) Dr. Pelaez also noted that J.V.'s vaccine reaction had never been observed by medical personnel. (*Id.*)

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<sup>22</sup> In Dr. Pelaez's affidavit, she does state that "[s]hortly after the vaccinations" it was "reported" to her that J.V. suffered an allergic reaction to the August vaccinations. (Ex. 28, ¶ 3.) But the affidavit provides no further details on how or when she received that alleged report. Significantly, Dr. Pelaez did not sign this affidavit until September of 2012, ten years after the events in question. I simply cannot believe that Dr. Pelaez actually had her own, independent memory in 2012 of a completely unrecorded telephonic "report" in 2002. Rather, it seems more likely that Dr. Pelaez in 2012 was simply stating what J.V.'s parents were telling her at that time in 2012, as they pursued this litigation. I find that Dr. Pelaez's records, or lack thereof, from August of 2000 through January 2001, to be more reliable than Dr. Pelaez's unexplained statement in 2012 that she received a "report" shortly after the vaccinations in August 2002.

Mrs. Valle further indicated that some time after the vaccinations of August 2, 2000, J.V. lost the ability to speak, “would just fall over” when placed upright, and continued his loss of activity. (Ex. 40, p. 2.) She further reported that he lost interest in all activities except music and basketball. (*Id.*) Mr. Valle asserted, however, that following his vaccinations, J.V. “was going in and out of consciousness” for about five days. (Ex. 34, p. 1.) He further indicated that in the second week after those vaccinations, J.V.’s parents noticed that J.V. stopped speaking and making eye contact, that he could barely walk, and that his behavior and cognitive skills regressed. (*Id.*)

The actual medical records, however, indicate that when a report of an allergic-type vaccine reaction was first made on January 2, 2001, the reported symptoms were limited to a rash with periorbital edema, loss of speech, and being “less active than usual.” (Ex. 20, pp. 28-29.) By that time, the only aspect of these symptoms characterized as ongoing was the loss of speech, which was itself initially noted as a speech delay in the context of a family history of speech delay. (Ex. 20, p. 27.)

Moreover, I note that there are further significant inconsistencies in the parental statements to physicians, and in their statements reported during the course of this litigation. As noted above, Mr. Valle described periods of J.V. “going in and out of consciousness” shortly after the August 2000 vaccinations (Ex. 34, p. 1), but Mrs. Valle’s statements do not mention such alleged episodes. As another example, there have been *several different* representations by J.V.’s parents as to *when* he stopped speaking. On November 16, 2000, Mrs. Valle reported that J.V. stopped speaking at some unspecified time “after last vaccines.” (Ex. 20, p. 27.) On January 2, 2001, Mrs. Valle reported that J.V. “would not speak” on the very next day after the August vaccinations. (Ex. 20, pp. 28-29.) But only two months later, one of J.V.’s parents reported that J.V. “ceased\*\*\*using words” (the notes say “seized,” but in context the physician’s note clearly appears to mean “ceased”) at some unspecified time *more than two weeks* after the vaccinations. (Ex. 19, p. 42.) On January 26, 2001, apparently a parent reported that J.V. was using “less than 4 words,” which is obviously inconsistent with not speaking at all. (Ex. 20, p. 40.) In her “narrative” prepared for this litigation, Mrs. Valle seemed to indicate it was only after “weeks went by” after the vaccinations that J.V. “seemed to have lost all ability to speak.” (Ex. 40, p. 2.) And in a statement prepared for this litigation, Mr. Valle stated that it was in the “second week” after the vaccinations when J.V.’s parents noticed that J.V. was not speaking. (Ex. 34, p. 1.) These various representations, made at various times, are obviously inconsistent with each other.

## V

### STATEMENTS OF MEDICAL DOCTORS OFFERED IN THIS CASE

In this case, although neither party submitted the type of detailed independent expert medical report commonly filed in Vaccine Act cases, both parties have submitted reports and statements from physicians prepared for this litigation, some of them opining concerning causation. Specifically, Petitioners have submitted statements by several of J.V.’s treating

physicians, while Respondent has submitted a report by one of her own medical officers. I will now summarize these opinions.

#### ***A. Medical opinions offered by Petitioners***

##### ***1. Gloria Pelaez, M.D.***

Dr. Pelaez was a member of the pediatric practice where J.V. was receiving care during the period in which J.V. was administered the vaccinations implicated by Petitioners' claim. (Exs. 14, 20, *generally*; *see also* Ex. 28, ¶¶ 1-2.) Although the records show that she is a medical doctor and practicing pediatrician, her qualifications are not otherwise a part of the record of this case.

On September 12, 2000, Dr. Pelaez signed an affidavit for this case in which she averred that "shortly after the vaccination," Mrs. Valle reported that J.V. suffered lethargy, allergic reaction, rash, "swelling of the eyes," and "welts on his neck and face." (Ex. 28, ¶ 3.) Dr. Pelaez, however, did not indicate in her affidavit on what date or under what circumstances that report occurred. Dr. Pelaez' *medical records* do not indicate any report of a rash and other allergic-type symptoms after the August vaccinations until January 2, 2001, approximately five months after the implicated vaccinations. (Ex. 20, p. 28.) Dr. Pelaez' records did indicate, though, that during visits on both November 16, 2000, and January 2, 2001, J.V.'s parents reported that J.V. stopped speaking after the August vaccinations. (Ex. 20, pp. 27, 28.) In that affidavit, Dr. Pelaez confirmed that she submitted a Vaccine Adverse Event Report System (VAERS) form, relating to J.V.'s August 2000 vaccinations. (Ex. 28, ¶ 3.) Dr. Pelaez, in fact, apparently filed two such forms. (Ex. 14, pp. 65, 99.) Dr. Pelaez, however, expressly noted, in both her medical record of January 2, 2001 and in the VAERS submissions, that none of J.V.'s alleged symptoms were observed by any medical personnel. (Ex. 20, p. 29; Ex. 14, pp. 65, 99.)

In her affidavit, Dr. Pelaez states, without further explanation, that at some unspecified point in time "this relationship [apparently, an alleged relationship between the vaccines and J.V.'s allergic reaction] was diagnosed," and J.V. was referred to Dr. Trevor Resnick, a pediatric neurologist. (Ex. 28, ¶ 6.) Dr. Pelaez, however, did not describe the circumstances surrounding this reported "diagnosis" of a relationship between J.V.'s vaccination and his condition. (Ex. 28.)

Further, in her affidavit, Dr. Pelaez did *not* state that it was *her* "diagnosis" or conclusion that J.V.'s vaccination had caused an allergic reaction, or harmed him in any way. (Ex. 28.)

##### ***2. Trevor Resnick, M.D.***

Dr. Resnick is a board-certified pediatric neurologist at Miami Children's Hospital. (Ex. 22, ¶ 1.) He began treating J.V. in March of 2001. (*Id.*, ¶ 2.) Dr. Resnick provided an affidavit, signed on September 25, 2012, in which he opined that J.V. experienced a vaccine-caused acute encephalopathy. (*Id.*, ¶¶ 4, 6-8.)

Specifically, Dr. Resnick indicated that when he first took J.V. as a patient, he was provided a medical history that indicated that J.V. "had been given a vaccination and that thereafter he had been lethargic and suffered a rash." (*Id.*, ¶ 3.) He further noted that on August

1, 2012, he recorded a history that J.V. experienced an allergic reaction to his 15-month vaccinations (noted as DTP, IPV, and Hib), displaying lethargy within four hours along with onset of rash, fever, and loss of speech occurring the following morning. (*Id.*, ¶ 4.) Dr. Resnick described the lethargy and loss of speech as continuing for several days. (*Id.*)

Although Dr. Resnick's records indicate that his *initial* assessment of J.V. was "social-communicative disorder" (Ex. 19, pp. 42-45; Ex. 14, p. 11), Dr. Resnick's affidavit indicated that as of August 2, 2012, his diagnosis of J.V. was "Acute Encephalopathy, loss of cognitive function, lethargy, [and] seizure." (Ex. 22, ¶ 4.) *Based on the history provided by J.V.'s parents*, Dr. Resnick opined that J.V.'s acute encephalopathy was vaccine-caused. (*Id.*, ¶ 6.) He characterized the likelihood of vaccine-causation as "medically presumptive" and "probable." (*Id.*, ¶ 8.)

Significantly, however, Dr. Resnick's affidavit did not acknowledge or explain his initial evaluation of J.V. in 2001, in which he concluded that J.V. had "social communicative disorder," and which made no mention of an acute encephalopathy. (Ex. 14, p. 11; Ex. 19, pp. 42-45.) Nor did Dr. Resnick's affidavit explain *why* he changed his diagnosis. (*See generally* Ex. 22.) The record of his evaluation of August 1, 2012, was not filed in this case.

### 3. **Ronaldo Nunez, M.D.**

Dr. Nunez is a medical doctor licensed to practice in the state of Florida. (Ex. 32, ¶ 1.) The *curriculum vitae* submitted by Petitioners for Dr. Nunez does not reflect any board-certified specialty, but indicates that Dr. Nunez undertook an internship and residency in pediatrics followed by a fellowship in allergy and immunology. (Ex. 32.1, p. 1.) Since the conclusion of his fellowship in 2011, Dr. Nunez has worked with the Asthma & Allergy Associates of Florida in Miami, Florida. (*Id.*) For this case, Dr. Nunez provided a letter (Ex. 27) dated December 19, 2012, as well as an affidavit (Ex. 32) dated July 26, 2013. Petitioners have also filed records from office visits with Dr. Nunez on July 11, 2012 (Ex. 25, pp. 10-13), and April 8, 2013 (Ex. 30).

In his record of July 11, 2012, which represents his first documented contact with J.V. in the record of this case, Dr. Nunez characterizes J.V. as experiencing developmental delay, and states that "I am uncertain of vaccines ever causing an allergic reaction which could contribute to [patient's] [developmental] delay." (Ex. 25, p. 13.) At that time, Dr. Nunez recommended further evaluation to determine whether an adverse vaccine reaction could be the cause of J.V.'s developmental delay. (*Id.*)

In his subsequent letter, Dr. Nunez characterized J.V. as having a history of "acute encephalitis vs. allergic reaction to vaccinations given at 15 months of age," suggesting that "allergic reaction to [the 15-month] vaccinations" was one of *two possibilities*. (Ex. 27.) He did not provide any further detail regarding either the source of this history, or J.V.'s actual medical course. (*Id.*) Rather, the primary purpose of this letter seems to have been to state Dr. Nunez's view that, notwithstanding J.V.'s possible vaccine allergy, and in contrast to his earlier suggestion of further evaluation, allergy testing to vaccines would be "of minimal to no benefit." (*Id.*)

In his subsequent affidavit, Dr. Nunez indicated that he has diagnosed J.V. with a “vaccine related disorder,” and developed a treatment plan for that disorder. (Ex. 32, ¶¶ 10-11.) He did not describe what he meant by “vaccine related disorder,” nor did he describe the treatment plan that he developed. (*Id.*) Although the “vaccine related disorder” diagnosis appears in his record of April 8, 2013, that record does not detail any treatment plan. (Ex. 30, p. 3.) To the extent that the affidavit cites “encephalopathy” in combination with an allergic reaction as contributing to J.V.’s developmental delay, this is presented *as a report from Mrs. Valle*. (Ex. 32, ¶ 6.) And indeed, the medical record created by Dr. Nunez likewise clearly indicates, in the “history of present illness” [“HPI”], that it was Mrs. Valle who reported that J.V. experienced “a vaccine related acute encephalopathy.” (Ex. 30, p. 1.) Dr. Nunez in his medical record did not actually opine that J.V. experienced a vaccine-related “encephalopathy.” (*See generally*, Ex. 30.)

Dr. Nunez’s affidavit also reiterated the position stated in his initial letter that allergy testing would not be useful, and further noted that the failure to retain the exact lot of vaccine from which J.V. was vaccinated impaired the establishment of any causal relationship. (Ex. 32, ¶¶ 11-13.) Nonetheless, Dr. Nunez characterized vaccine-causation of J.V.’s condition as “presumed” based on a “preponderance of evidence,” which evidence he left entirely undescribed. (Ex. 32, ¶ 11.)

Dr. Nunez did not state that he reviewed any of J.V.’s prior medical records, nor any findings on physical examination related to the stated diagnosis of a vaccine-related disorder. (Ex. 32.) None of Dr. Nunez’s subsequent records or submissions indicate that he engaged in any follow-up evaluation regarding potential vaccine causation, as called for after his initial evaluation. And indeed he subsequently ruled out the usefulness of further testing.

Moreover, Dr. Nunez’s change of opinion is itself entirely unexplained. Rather, it appears that the entirety of Dr. Nunez’s final opinion is based on Mrs. Valle’s ten-years-after-the-fact history, as well as the above-described affidavits by Drs. Resnick and Pelaez, which are themselves based entirely on Mrs. Valle’s later account. (Ex. 32, ¶¶ 4, 6, 11.)

#### **4. Roberto Tuchman, M.D.**

Dr. Tuchman is a neurologist who first saw J.V. on July 27, 2004, to provide a second opinion to Dr. Resnick’s evaluation. (Ex. 20, pp. 60-61; Ex. 31, p. 1.) He indicated that he confirmed J.V.’s *autism diagnosis* per DSM-IV criteria. (*Id.*) Although Dr. Tuchman did not provide any affidavit or letter as did Drs. Pelaez, Resnick, and Nunez, Petitioners filed a consultation report by Dr. Tuchman dated June 28, 2013, which specifically indicated that the consultation was sought for purposes of advancing Petitioners’ vaccine injury claim. (Ex. 31, p. 1.) Dr. Tuchman’s credentials are not a part of the record of this case.

Dr. Tuchman reported a history in which J.V. experienced lethargy within four hours of receiving his 15-month vaccinations, along with rash, fever, continued lethargy and loss of speech occurring the following day. (Ex. 31, p. 1.) His diagnosis included an autism spectrum disorder, chronic encephalopathy, and intellectual disability. (Ex. 31, p. 5.) In his summary, Dr. Tuchman explained that J.V. meets the criteria for autism spectrum disorder. (*Id.*) Although he

stated that the history provided to Dr. Tuchman indicates that J.V.'s ASD "presumably stems from allergic reaction to vaccines"<sup>23</sup> (Ex. 31, p. 1), during his consultation with Petitioners he stated, to the contrary, that he "explained to the family that his diagnosis is autism spectrum disorder and that I *cannot from the history and records reviewed give a reason for causation*" (Ex. 31, p. 6).

Significantly, although Petitioners initially filed Dr. Tuchman's consultation report in response to an order to file an expert opinion (*see* ECF Nos. 72, 73), in a subsequent status report Petitioners indicated that they were relying on the statements of Dr. Resnick, Dr. Nunez and Dr. Palaez. (ECF No. 97.) They did not indicate any intent to rely on Dr. Tuchman's previously-filed consultation report. (*Id.*)

## ***B. Medical opinion offered by Respondent***

### ***1. Catherine Shaer, M.D.***

Dr. Shaer is a board-certified pediatrician. (Ex. E, p. 1.) From 1981 to 1999, she worked as a practicing physician. (*Id.*, pp. 3-4.) Since 2000, she has worked for the federal government in various research and review capacities. (*Id.*, pp. 1-3.) As of September of 2013, when her report and CV were filed, she had worked at the Division of Vaccine Injury Compensation within the Department of Health and Human Services since 2008. (*Id.*, p. 2.)

Following an extensive recitation of J.V.'s relevant medical history, Dr. Shaer's report concludes that Petitioners' contentions are not supported by the medical records. (Ex. D.) Specifically, she notes that there was no contemporaneous description of any vaccine reaction, and that the reaction later described by Ms. Valle is consistent with a mild or transient reaction only. (*Id.*, pp. 5-7.) Ultimately, Dr. Shaer opined as follows: "Based on the records submitted it is my medical opinion that [J.V.] possibly experienced a transient, mild reaction to vaccines but the record is insufficient to so opine to a reasonable degree of medical certainty. I do opine to a reasonable degree of medical certainty that his communication disorder/autism was not caused by vaccines received on 8/2/2000." (*Id.*, p. 7.)

## **VI**

### **ISSUES TO BE DECIDED**

In this case, the Petitioners' sole allegation of entitlement to a Program award, according to their Proposed Findings of Fact and Conclusions of law filed on April 24, 2015 (ECF No. 117), is that J.V. experienced a "table encephalopathy" following the DTaP vaccination that he received on August 2, 2000 (ECF No. 117, p. 13). As described above, a Table Injury carries a

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<sup>23</sup> Dr. Tuchman's statement regarding "presumed" vaccine causation appears to be a summary of what was *reported to* Dr. Tuchman, not his own diagnosis. (Ex. 31, p. 1.) The statement appears in the "History" section of Dr. Tuchman's report (*id.*), and does not appear in his "Impression" section (*id.*, pp. 5-6), in which he provides his own assessment of J.V.'s condition.

presumption of causation. Petitioners need establish only that J.V. experienced an injury meeting the definition of “encephalopathy,” under the applicable regulation, during the applicable timeframe. In this case that timeframe is 72 hours. For the reasons described below, I find that Petitioners have *failed* to meet their burden.<sup>24</sup>

J.V.’s medical records, in fact, do *not* show symptoms consistent with any aspect of the applicable Table definition of “encephalopathy.” And the additional statements later offered by J.V.’s parents, in the course of this litigation, were unsupported with regard to their accounts of additional, more severe, symptoms. In addition, opinions offered by treating physicians in this case were also unpersuasive, because they relied not on the contemporaneous medical records, but instead on the later factual allegations of J.V.’s parents, which I have found not to be reliable.

In addition to their sole claim set forth in their Proffered Findings, of a “table encephalopathy,” Petitioners have also suggested at times that J.V.’s vaccinations of August 2, 2000, “caused-in-fact” harm to J.V. Petitioners, however, have completely failed to offer any explanation for *how* J.V.’s injury could have been vaccine-caused. Moreover, the cause-in-fact claim fails for the same reason as the Table injury claim - - that is, neither the allegations made by J.V.’s parents nor the medical opinions offered are substantiated by the medical records.

These same shortcomings likewise prevented any finding that J.V. experienced a Table anaphylaxis. A brief analysis of this claim is included, because Table anaphylaxis was claimed in certain of Petitioners’ earlier pleadings.<sup>25</sup>

## VII

### PETITIONERS HAVE NOT DEMONSTRATED A TABLE INJURY

#### A. *Legal standard: “Table Injury Encephalopathy”*

For petitions such as this one, filed after the modifications to the Vaccine Injury Table that went into effect in 1995 and 1997, “encephalopathy” exists as a Table Injury for DTaP

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<sup>24</sup> Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a “preponderance of the evidence.” § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

<sup>25</sup> Although Petitioners also mentioned “encephalitis,” another Table injury listed along with “encephalopathy for the DTaP vaccination,” in their amended petition (*see* ECF No. 67), neither J.V.’s medical records nor any of the medical opinions submitted in this case indicates that J.V. ever experienced an “encephalitis.” There is therefore no reason to address it further. “The special master or court may not make such a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a)(1).

vaccinations.<sup>26</sup> 42 C.F.R. § 100.3(a)(II)(B). According to the applicable regulation, under the “qualifications and aids to interpretation” (“QAI”) section, an “encephalopathy” may be compensated as a Table Injury where the vaccinee experiences an “acute encephalopathy” followed by a “chronic encephalopathy” that persists for at least six months. (42 CFR § 100.3(b)(2).) An acute encephalopathy is “one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).” 42 C.F.R. § 100.3(b)(2)(i).

Under the controlling regulatory definition of an “acute encephalopathy,” for a child younger than 18 months of age presenting without an associated seizure event, an acute encephalopathy is indicated “by a significantly decreased level of consciousness\*\*\*lasting for at least 24 hours.” 42 C.F.R. § 100.3(b)(2)(i)(A). A significantly decreased level of consciousness is indicated by the presence of one of three clinical signs for a period of at least 24 hours: “(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).” 42 C.F.R. § 100.3(b)(2)(i)(D). Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are *not*, alone, or in combination, a demonstration of an acute encephalopathy. 42 C.F.R. § 100.3(b)(2)(i)(E) (emphasis added).

A chronic encephalopathy is defined in the QAI as “a change in mental or neurologic status, first manifested during the applicable time period, [that] persists for a period of at least 6 months from the date of vaccination.” 42 C.F.R. § 100.3(b)(2)(ii). If a person returns to a typical neurologic state after suffering an acute encephalopathy, he or she is not presumed to have suffered residual neurologic damage and “any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy.” *Id.*

***B. The facts of this case do not meet the Table requirements for encephalopathy.***

***1. The medical records do not reflect an “acute encephalopathy.”***

Following the vaccinations of August 2, 2000, J.V. was not seen by his pediatrician again until November 16, 2000, three months after his alleged vaccine reaction. (Ex. 20, p. 27.) At that time, J.V.’s mother reported only that J.V. stopped speaking at some unspecified point after

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<sup>26</sup> The statute itself contains a version of the Vaccine Injury Table that applied to vaccinations administered prior to the enactment of the Program and for several years after that enactment. *See* § 300aa-14(a). However, the Vaccine Injury Table has been modified at times, with those modifications becoming applicable to petitions filed after the date of those modifications. § 300aa-14(c)(4); *see, e.g.*, 60 Fed. Reg. 7678 (1995); 62 Fed. Reg. 7685, 7688 (1997); *O’Connell v. Shalala*, 79 F.3d 170 (1<sup>st</sup> Cir. 1996); *Terran v. HHS*, 195 F. 3d 1302 (Fed. Cir. 1999). The 1995 and 1997 Table modifications, cited above, significantly altered the “Table Injury” categories with respect to the DTaP vaccination, from the version of the Table contained in the statute. The portion of the Table applicable to this case, listing “encephalopathy” as a Table Injury for the DTaP vaccination, appears at 42 C.F.R. § 100.3(a)(II)(B) (10-1-97 edition of C.F.R. -- all C.F.R. references in this Decision will be to the 10-1-97 edition of the C.F.R.).



his vaccinations. (*Id.*) That speaking issue, however, was linked to a strong family history of speech delay, and J.V. was referred only for an audiology evaluation. (*Id.*) It was not until January 2, 2001, that J.V.'s mother reported an acute reaction following J.V.'s 15-month vaccinations. (Ex. 20, p. 28.) At that time, his symptoms were reportedly mild swelling around his eyes (periorbital edema), an unspecified type of rash, "less activity than usual," and loss of speech. (Ex. 20, pp. 28-29.)

The medical records made during J.V.'s visits on November 16, 2000, and January 2, 2001, visits that occurred months after the August 2000 vaccinations, cannot fairly be considered records truly "contemporaneous" to those vaccinations. For this reason, they do not carry as much weight as a more timely report of symptoms would have. *See, e.g., Vergara v. HHS*, 08-882V, 2014 WL 2795491, \*4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded later in medical histories, affidavits, or trial testimony.").

However, even *accepting* at face value the symptoms as reported in the medical records of November 16, 2000, and January 2, 2001, they still do not establish the presence of an "acute encephalopathy" as defined by the QAI. "The symptoms associated with an acute encephalopathy are neither subtle nor insidious." *Waddell v. HHS*, No. 10-316V, 2012 WL 4829291, \*6 (Fed. Cl. Spec. Mstr. Campbell-Smith September 19, 2012). Moreover, "[t]he hospitalization requirement underscores how serious the symptom presentation must be after vaccination to merit classification as a Table encephalopathy." *Waddell*, 12 WL 4829291 at \*7. In this case, however, J.V.'s mother specifically confirmed that she did *not* seek medical attention at the time these alleged symptoms presented, wishing instead to see "if child would improve on his own and return to normal." (Ex. 20, p. 29.)

Most importantly, neither the November 2000 nor the January 2001 record describes anything *close* to the type of "acute encephalopathy" described in the applicable definition set forth above. There is no description at all of a "significantly decreased level of consciousness," much less one "lasting for at least 24 hours." There is no description of "decreased or absent response to environment," "decreased or absent eye contact," or "inconsistent or absent responses to external stimuli."

Significantly, "in amending the QAI, the Secretary of Health and Human Services included the specific clinical signs at 42 C.F.R. § 100.3(b)(2)(i)(D) in an effort to 'clearly distinguish infants and children with brain dysfunction from those with transient 'lethargy,' noting that the severity and duration of 'more serious impairment of consciousness that is the hallmark of encephalopathy' differentiating it from the 'diminished alertness and motor activity' of lethargy following a fever or illness." *Blake v. HHS*, 2014 WL 2769979, at \*6 (Fed. Cl. Spec. Mstr. May 21, 2014) (quoting 60 Fed. Reg. 7678, 7687 (Feb. 8, 1995)). J.V.'s reported decrease in activity would seem to fall in the latter category rather than the former. Indeed, in her own VAERS form, Mrs. Valle indicated only that J.V. was "very tired like he had the flu." (Ex. 14, p. 66.)

Nor does J.V.'s alleged loss of speech following vaccination point in itself to "a decreased level of consciousness." For example, in *Waddell v. HHS*, the Special Master

determined that a child's loss of verbal skills did not fall within the QAI definition of "significantly decreased level of consciousness," noting in particular that a "lack of responsiveness did not translate into a lack of consciousness." *See Waddell*, 2012 WL 4829291, at \*10. In this regard it is, again, particularly significant that J.V.'s mother decided to wait more than three months before raising J.V.'s loss of speech with his pediatrician. And when she did later report that speech loss, she did so in the context of a family history of speech delay. Moreover, when J.V.'s speech loss was first reported his pediatrician apparently did *not* perceive any neurologic emergency, instead referring J.V. only for a hearing evaluation. This suggests that the change in J.V.'s speech was not as abrupt or severe as Petitioners later contended, nor as striking as would denote a significant decrease in consciousness. In that regard, it is also significant that J.V.'s language deficit was subsequently attributed to his ASD. (*See, e.g.*, Ex. 20, p. 62.)

**2. *Petitioners' later allegations of additional, more severe, symptoms are unsubstantiated.***

It is true that some of Petitioners' narrative statements filed during this litigation have subsequently described symptoms much more severe than those reported in the November 2000 and January 2001 records, namely a loss of consciousness, which might be more in keeping with the QAI. However, I decline to credit those Petitioners' statements in this regard. I find that if such severe symptoms of loss of consciousness and the like in fact took place abruptly after the August 2000 vaccines, as alleged by Petitioners in this litigation, the Petitioners would surely have brought J.V. in for medical attention, not waited for three months to do so.<sup>27</sup> I therefore find that there is insufficient evidence to establish that J.V. had a vaccine reaction that encompassed these later-reported symptoms.

Medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed.Cir.1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters frequently accord more weight to the medical records. *See, e.g., Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993) ("[W]ritten documentation recorded by a disinterested person at or soon

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<sup>27</sup> I stress that I am *not* suggesting that J.V.'s parents were negligent in failing to bring J.V. back to the doctor's office in early August of 2000, after he supposedly suffered an abrupt loss of speech, loss of consciousness and the other symptoms later alleged to have occurred shortly after the August 2000 vaccinations. My conclusion, rather, is that most likely these alleged symptoms of abrupt speech loss and loss of consciousness simply *did not* occur in the abrupt manner or timeframe alleged by J.V.'s parents in the course of this litigation, or else J.V.'s parents, as good, caring parents, *would have brought J.V. back to the physician at that time*, rather than waiting until November 16, 2000, as they actually did. To be sure, I also am *not* concluding that these later allegations by the Petitioners were *intentionally* untruthful. I simply cannot credit the *accuracy* of these later memories of J.V.'s parents, when compared to the actual records (or lack thereof) in late 2000 and January 2001. For example, based on the medical record made on November 16, 2000, I *accept* that *sometime* between August 2 and November 16, J.V. lost speech. But if the speech loss had been abrupt, within 72 hours of the August 2 vaccinations, J.V.'s parents would certainly have taken J.V. back to the doctor at that time.

after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.”).

To be sure, “it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.” *Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff’d*, 968 F.2d 1226 (Fed. Cir. 1992)). However, in balancing these considerations, special masters in this Program have traditionally declined to credit later testimony over contemporaneous records unless it is “clear, cogent, and consistent.” *See, e.g. Stevens v. HHS*, 90-221V, 1990 WL 608693, at \*3 (Cl. Ct. Spec. Mstr. 1990); *see also Vergara v. HHS*, 08-882V, 2014 WL 2795491, at \*4 (Fed. Cl. Spec. Mstr. July 17, 2014) (“Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.”) *See also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that “the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight.”).

Here, Mr. and Mrs. Valle’s later accounts are utterly unsupported by any contemporaneous medical records. While Mr. and Mrs. Valle assert that they contacted J.V.’s pediatric office immediately following his vaccine reaction, there is no record showing such a call.

Moreover, Petitioners’ accounts do not have the type of consistency necessary to suggest that they may be relied upon in preference to the relatively contemporaneous medical records. This is particularly true with regard to the most critical aspect of Petitioners’ account, regarding J.V.’s alleged loss of consciousness. Whereas Mr. Valle asserts that J.V. actually lost consciousness during the first five days following his vaccination (Ex. 34, p. 1.), Mrs. Valle made no such allegation. Rather, she states only that J.V. was sleepy or less active. (Ex. 40, p. 2.) Mrs. Valle’s less-severe account is closer to what is reflected in the later medical records. Further, there are simply many additional significant inconsistencies, as noted above, in the parental statements to physicians, and in their statements reported during the course of this litigation. For example, there have been *several different* representations by J.V.’s parents as to *when* he stopped speaking. On November 16, 2000, Mrs. Valle reported that J.V. stopped speaking at some unspecified time “after last vaccines.” (Ex. 20, p. 27.) On January 2, 2001, Mrs. Valle reported that J.V. “would not speak” on the very next day after the August vaccinations. (Ex. 20, pp. 28-29.) But only two months later, one of J.V.’s parents reported that J.V. “ceased\*\*\*using words” (the notes say “seized,” but in context the physician’s note clearly appears to mean “ceased”) at some unspecified time *more than two weeks* after the vaccinations. (Ex. 19, p. 42.) On January 26, 2001, apparently a parent reported that J.V. was using “less than 4 words,” which is obviously inconsistent with not speaking at all. (Ex. 20, p. 40.) In her “narrative” prepared for this litigation, Mrs. Valle seemed to indicate it was only after “weeks went by” after the vaccinations that J.V. “seemed to have lost all ability to speak.” (Ex. 40, p. 2.) And in a statement prepared for this litigation, Mr. Valle stated that it was in the “second week” after the vaccinations when J.V.’s parents noticed that J.V. was not speaking. (Ex. 34, p. 1.)

These various representations, made at various times, are obviously quite inconsistent with each other.

Thus, I do not find that Petitioners' narrative statements provided during the litigation of this case provide any substantial support for their claim. Most of the symptoms they describe are unrelated to a Table encephalopathy as defined by the QAI, and cannot be corroborated by any contemporaneous medical records. On the critical question of J.V.'s level of consciousness, only J.V.'s father alleged any loss of consciousness, but his assertion in that regard is not supported by either the medical records or by Mrs. Valle's accounts, and cannot be credited as accurate.<sup>28</sup>

**3. *The physician statements offered by Petitioners are similarly insufficient to establish an "acute encephalopathy."***

Although Petitioners have come forward with much later statements by J.V.'s treating physicians, which do appear to accept the later allegations of J.V.'s parents as true, in the present context this is of no moment. Such opinions do *not* serve to substantiate Petitioners' statements, because they were completely based on the statements prepared during the litigation by the Petitioners themselves. *See, e.g., Bradley v. HHS*, 991 F.2d 1570, 1574 (Fed. Cir. 1993) (noting that "although medical opinions were offered in support of [petitioners'] testimony, those medical opinions were based largely on that testimony itself and, therefore, the special master could reasonably conclude that the medical opinions did not qualify to substantiate that testimony.")

It is true that often in Vaccine Act cases, the opinion of treating physicians are accorded significant weight, because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). That deference, however, is premised on the treating physician's ability to observe the patient both before and after the alleged vaccine injury. *Nuttall v. HHS*, 122 Fed. Cl. 821, 832 (Fed. Cl. 2015). "The reasoning

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<sup>28</sup> It is also worth noting that to the extent that J.V.'s parents aver that he experienced a dramatic *regression* of skills after 15 months, developmental milestones prior to that time are only sparsely noted within J.V.'s medical records, making it difficult to substantiate the claim that J.V. regressed. Moreover, at the time Mrs. Valle reported a regression to Dr. Pelaez, Dr. Pelaez seemed to characterize J.V.'s prior speech development as minimal, noting that he had stopped saying "the few words that he was already saying." (Ex. 20, p. 29.) This is consistent with earlier records which note, for example, that as of the date on which the implicated vaccinations were administered at 15 months, J.V. was reported as being able to say only "mama," "daddy," and "what's that." (Ex. 20, p. 25.) And even *subsequent* to the implicated vaccinations, as of January 26, 2001, J.V. was similarly noted to have "less than 4 words." (Ex. 20, p. 40.) In that regard, the medical records do *not* seem to support Petitioners' claim of a major speech regression. Indeed, the record of January 26, 2001, seems to *contradict* the parents' allegations that J.V. lost all speech in August 2000. In other words, "less than 4 words" on January 26, 2001, seems to be comparable to the limited speech that J.V. had on August 2, 2000. (*See* Ex. 20, p. 25.) But in any event, such a speech regression, if it did occur, would not be dispositive as to the "Table encephalopathy" issue, since it was later accounted for in J.V.'s ASD diagnosis. (*See, e.g.,* Ex. 9; Ex. 20, pp. 61-62.)

underlying the finding that opinions of treating physicians should be given particular weight does not apply when \*\*\*the treating physician only saw the patient after the injury and based his opinion on the same evidence as relied upon by the retained experts.” *Id.*

Regardless of what Dr. Pelaez and J.V.’s other physicians ultimately came to believe based on the retrospective reports of J.V.’s parents, all of the physician statements offered by Petitioners are explicitly based, *not* on first hand observation of J.V.’s alleged injury, but on the *very same after-the-fact representations by Petitioners* which I have determined are not credible. (See Section VII(B)(2), above.) Thus, they are unpersuasive. See also, *Dobrydnev v. HHS*, 566 Fed. Appx. 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that “when an expert assumes facts that are not supported by preponderance of the evidence, a finder of fact may properly reject the expert’s opinion”); *Snyder v. HHS*, 88 Fed. Cl. 706, 745 n. 67 (2009) (emphasizing that a statement of a treating physician is not “sacrosanct” and can be rebutted).

Moreover, I find it particularly significant that Dr. Paelaez, Dr. Resnick, and Dr. Nunez have all offered opinions for this litigation that are contrary to the opinions expressed in their original treatment records, and have done so years after the fact without any explanation whatsoever. I give far greater weight to the impressions stated in their original treatment records than I do to the later unexplained and litigation-driven opinions. See, e.g., *Broekelschen v. HHS*, 618 F.3d 1339, 1346-49 (Fed. Cir. 2010) (approving of the special master’s decision to accord more weight to earlier and more detailed medical records over later records that did not reflect any reasoning for the doctors’ statements); see also, *Cucuras v. HHS*, 993 F.2d 1525 (Fed. Cir. 1993) (noting that “medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.”). In their original records, *none* of J.V.’s pediatricians suggested that J.V. experienced an “acute encephalopathy,” or otherwise opined that J.V.’s neurologic condition was in any way related to his vaccinations.

***C. Petitioners have not established a Table Injury anaphylaxis.***

In earlier pleadings, Petitioners had briefly raised claims regarding “anaphylactic shock” (e.g., Ex. 40, p. 1.), which is also a Table Injury when experienced within four hours after receiving certain vaccinations, including the DTaP. (See 42 C.F.R. § 100.3(a)(II)(A).) I note here, in the interest of completeness, that there is, again, insufficient evidence supporting this claim.

Pursuant to the applicable QAI, anaphylaxis or anaphylactic shock is defined as “an acute, severe, and potentially lethal systemic allergic reaction.” 42 C.F.R. § 100.3(b)(1). Such reactions begin minutes to a few hours after exposure, and include symptoms such as airway obstruction, cyanosis, hypertension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. (*Id.*) To qualify as a Table Injury, an anaphylaxis must occur within four hours of vaccination. 42 C.F.R. § 100.3(a)(II)(A).

Obviously, since I have found, as discussed above, that there is insufficient evidence supporting Petitioners' accounts of a significant reaction soon after the vaccinations in question, this likewise precludes a finding that J.V. experienced an acute and severe reaction constituting an anaphylaxis. But in any event, even if those accounts were to be credited, I also note that none of the symptoms described by Mrs. Valle overlap with the symptoms identified in the QAI. Nor is there sufficient evidence to suggest that J.V.'s alleged vaccine reaction occurred within four hours of his vaccination, as required for a Table anaphylaxis. Indeed, Mrs. Valle's account suggests that on the evening after the vaccinations, J.V. was doing well and was merely sleepy at the time she placed him in bed for the night. (Ex. 40.) She specifically noted that he did not have any fever or difficulty breathing. (*Id.*) Rather, by her own account, J.V.'s additional symptoms did not manifest until the next morning, (*id.*), not within the required four-hour period.

## VIII

### **PETITIONERS HAVE NOT DEMONSTRATED THAT J.V. EXPERIENCED A NEUROLOGICAL INJURY "CAUSED-IN-FACT" BY HIS VACCINATIONS**

As noted in Section I, above, having failed to establish that J.V.'s injury meets the strict parameters of a *Table Injury*, Petitioners at times have alternatively suggested that J.V.'s injury was *caused-in-fact* by his vaccinations of August 2, 2000. I will, therefore, in the interest of completeness, briefly explain why any such claim would necessarily fail.

#### **A. Legal standard: the Althen test**

For "cause-in-fact" cases, the U.S. Court of Appeals for the Federal Circuit declared in *Althen* that it is a petitioner's burden:

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Althen v. HHS*, 418 F.3d 1274, at 1278 (Fed. Cir. 2005) (citations omitted).

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; [and] (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions

issued prior to *Althen* involving “causation-in-fact” issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee’s own injury. *See, e.g., Kuperus v. HHS*, No. 01-0060V, 2003 WL 22912885, at \*8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, No. 96-518V, 2002 WL 31441212, at \*18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the “can cause” requirement, and Prong 2 of *Althen* is the “did cause” requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, No. 02-0738V, 2007 WL 2296047, at \*24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, No. 06-0120V, 2008 WL 3845155, at \*25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the “can it?/did it?” test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the *type* of vaccination in question can cause the *type* of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the *particular* vaccination did cause the *particular* condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is “more probable than not” that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner’s case must be established by a “preponderance of the evidence.” § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, *in this case* the overall evidence falls far short of demonstrating that it is “more probable than not” that any of the vaccines that J.V. received on August 2, 2000, contributed to the causation of his tragic neurodevelopmental disorder.

***B. The facts of this case do not meet the Althen standard.***

***1. Althen Prong 1***

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. In this case, although some of J.V.’s treating physicians ultimately provided brief written opinions indicating that J.V.’s condition was likely vaccine-caused, none offered *any explanation* of how any of J.V.’s vaccines *could have* caused the type of condition from which he suffers. For example, to the extent that Dr. Nunez posited an allergic reaction, he appears to have based his conclusion solely on the *alleged* temporal relationship between vaccination and onset *in this case*. (Ex. 32, ¶ 11.) Indeed, Dr. Nunez characterized J.V.’s condition as a “presumed vaccine related condition,” and discounted the possibility that J.V. could undergo relevant allergy tests to confirm that he had such an allergy. (*Id.*) This is inadequate. *See, e.g., LaLonde v. HHS*, 746 F.3d 1334, 1341 (Fed. Cir. 2014) (holding that “the basis for Ms. LaLonde’s petition reduces to a temporal relationship between the administration of the DTaP vaccine and M.L.’s focal brain injuries. As we have stated before, a temporal correlation alone is not enough to demonstrate

causation.”); *see also Althen*, 418 F.3d at 1278 (“Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.”). Nor, for that matter, did Dr. Nunez present a theory by which J.V.’s *ongoing neurological condition*, including his ASD, could be a sequela of such an allergic reaction.

Nor do Petitioners find adequate support in any of the other exhibits, including the vaccine information sheets, that they filed in this case. (*See* Exs. 35-39.) Although these sheets reference both allergic reactions to vaccines as well as the potential for brain injury, they do not address the resulting brain injury or its manifestation in sufficient detail to persuasively support Petitioners’ contention that a condition of the type that J.V. suffers could have been vaccine-caused. (*Id.*) That is, they do not support the contention that vaccines could result in a presentation similar to J.V.’s history, including ASD or an ASD-like symptoms.

In sum, absent a Table presumption, Petitioners have effectively left their *theory of causation* entirely unstated.

## 2. Althen Prong 2

Under Prong 2, the Petitioners need to show that it is “more probable than not” that one or more of J.V.’s vaccination of August 2, 2000, *did* initially cause J.V.’s *own* condition. But this they have failed to do for all of the same reasons as described above. That is, J.V.’s *documented* medical history fails to substantiate Petitioners’ claim that J.V. experienced a severe vaccine reaction at all, let alone that such a reaction would constitute an encephalopathy significant enough to account for his ongoing neurological condition. Indeed, all of the medical opinions offered in support of that contention rely heavily, if not exclusively, on the *later* histories provided by J.V.’s parents during this litigation. Significantly, in the contemporaneous medical records, J.V.’s pediatrician expressly noted, on two occasions, that J.V.’s alleged vaccine reaction was not witnessed by any medical professional. And at least one physician whose report was submitted by Petitioners, Dr. Tuchman, specifically indicated that the history provided was *inadequate* to determine causation. (Ex. 31, p. 6.)

## 3. Althen Prong 3

Since I have explained why Petitioners have failed to satisfy the first and second prongs of *Althen*, I need not discuss why Petitioners’ case also fails to satisfy the third prong. However, I note that Petitioners’ claim fails on this prong for the very same reason as noted regarding Prong 2. The temporal relationship alleged between J.V.’s injury and his vaccination is simply not supported by the *contemporaneous* medical records.<sup>29</sup>

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<sup>29</sup> I note that I have rejected the Petitioners’ claims in this case primarily because their claims are contradicted by the medical records (or lack thereof) made in late 2000 and early 2001, and because their proffered physician statements offer *no explanation at all* of *why* such physicians might think that J.V. suffered a “Table Injury encephalopathy” or that he has any vaccine-caused condition. Therefore, I have rejected Petitioners’ claim even without considering the expert medical opinion of Dr. Shaer provided by Respondent. I do note, here, however, that



#### 4. *This is not a close case*

In *Althen*, the Federal Circuit indicated that the Vaccine Act involves a “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Althen*, 418 F.3d at 1280. Accordingly, I note here that this case is ultimately *not* a close call. For all the reasons set forth above, I find that, based on the record as a whole, Petitioners’ claim was *not at all* persuasive.<sup>30</sup>

## IX

### CONCLUSION

The record of this case demonstrates plainly that J.V. and his family have been through a tragic ordeal. I have also studied the records describing J.V.’s medical history, and the efforts of his family in caring for him. Based upon those records, the great dedication of J.V.’s family to his welfare is readily apparent to me.

Nor do I doubt that J.V.’s parents are sincere in their belief that one or more of J.V.’s vaccinations played a role in causing J.V.’s severe neurological disorder, which has been characterized as an Autism Spectrum Disorder. After studying the extensive evidence in this case, I find no persuasive evidence that J.V. suffered a Table Injury, or that his vaccinations played any role in causing any disorder. Nevertheless, I conclude that the Petitioners filed this petition in good faith.

Thus, I feel deep sympathy for the Valle family. Further, I find it unfortunate that my ruling in this case means the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to families of *all* autistic children, regardless of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their autistic children, and all are deserving of sympathy and admiration. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by Table Injury or presumption or by preponderance of “causation-in-fact” evidence, to a listed vaccine. In this case, the evidence advanced by the Petitioners has fallen far short of demonstrating such a link.

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Dr. Shaer’s opinion, more detailed and better explained than the brief physician statements upon which Petitioners rely, would add yet another reason to reject Petitioners’ claim.

<sup>30</sup> It should be noted that in this case the Petitioners never carried their burden of making a “*prima facie*” case showing that J.V. suffered a vaccine-caused or vaccine-aggravated injury. Therefore, the burden *never shifted* to Respondent to demonstrate that J.V.’s condition was “due to factors unrelated to the administration of the vaccine.” §300aa-13(a)(1)(B).

Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on J.V.'s behalf.<sup>31</sup>

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George L. Hastings, Jr.  
Special Master

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<sup>31</sup> In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.